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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/669,294 | 09/23/2003 | James L. Hobart | SCI-00602 | 4649 |

7590 05/19/2005

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EXAMINER

PEFFLEY, MICHAEL F

| ART UNIT | PAPER NUMBER |
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3739

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,294

Applicant(s)

HOBART ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-31 and 48-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-31 and 48-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/22/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Specification

The disclosure is objected to because of the following informalities: the most current status (i.e. US Patent Number) of the related applications cited in the first paragraph must be provided.

Appropriate correction is required.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Applicant had canceled claims 32-47 in the amendments of September 23, 2003, then attempted to reinstate those claims in the amendment of December 17, 2003. Applicant cannot reinstate canceled claims. As such, claims 32-47 have been renumbered by the examiner as claims 48-63, each being provided with the parenthetical claim identifier "new" as well as the appropriate dependency resultant from the renumbering of the claims.

Claims 48-50 are objected to because of the following informalities: claim 48 recites "truck fiber" in line 6, and should read "trunk fiber"; claim 49 is unclear with the phrase "wherein guide structure is configured be bent" and should read "wherein the guide structures are configured to be bent"; claim 50 should recite "wherein the input end". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Trelles (5,522,813).

Trelles discloses a laser system that comprises a laser source (20) for generating laser light in bursts, each of the burst comprising a plurality of individual pulses (see col. 3, lines 9-15). Trelles also discloses an applicator (22) for delivering the laser pulses to vascular tissue. The energy per pulse and frequency of the bursts is also disclosed by Trelles (col 3, lines 3-15).

Claims 19-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Loeb et al (5,984,915).

Loeb discloses a laser system comprising a laser source that provides bursts of laser energy, each burst including a plurality of laser pulses (see col. 8, line 44 to col. 9, line 5). Loeb disclose the same energy per pulse, as well as pulse durations, separation and optical fiber diameter in this section of the patent.

Claims 19-26 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Colvard et al (5,738,677).

Colvard et al provide a laser system that includes a laser source (60) that provides laser energy in a series of bursts, each burst including a plurality of pulses (col. 7, lines 25-35). Colvard et al also disclose a flexible optical fiber for delivering the laser energy, the fiber having a diameter in the range set forth by applicant (col. 8, lines 30-40). Colvard et al further disclose per pulse energies, frequencies and pulse durations that are within the range set forth by applicant (col. 7, lines 25-35). The probe includes a distal applicator (Figure 5) that includes a structure (106) for shielding light from tissue, and a means (110) to control the distance of the laser beam fired from the optical fiber. This structure (i.e. cap 106 and lens 110) is deemed to be a "shroud" structure as recited in applicant's claim 30.

Claim Rejections - 35 USC § 103

Claims 22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trelles ('813) in view of the teaching of Loeb et al ('915).

The Trelles device has been previously addressed. While Trelles discloses various pulse parameters for the system, there is no explicit disclosure of the specific burst separation, pulse separation and/or pulse widths.

Also addressed previously, Loeb et al disclose a laser device used for the same purpose (i.e. coagulation of blood vessels). In particular, Loeb specifically teach of pulse parameters that are within the range of parameters for treating vascular tissue as set forth in applicant's claims.

To have provided the Trelles system with any reasonable pulse characteristics, such as pulse separation and pulse duration, for the treatment of vascular tissue would

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have been an obvious consideration for one of ordinary skill in the art, particularly in view of the teaching of Loeb et al who disclose pulse parameters for treating vascular tissue that are well within the applicant's cited range.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Colvard et al ('677) or Loeb et al ('915).

The Colvard et al and Loeb et al devices have been previously addressed. While both of these device disclose flexible optical fibers for delivering laser energy, neither one specifically discloses a silicon or sapphire optical fiber.

The examiner takes official notice that the use of silicon and sapphire in making flexible optical fibers is generally very well known in the art. It is also noted that Colvard et al disclose the use of a silicon fiber used in the probe end of the applicator (col. 9, line 1).

To have formed the Colvard et al or the Loeb et al flexible optical fiber from any well known material, such as silicon or sapphire, would have been an obvious design expedient for one of ordinary skill in the art, particularly in view of the well-known use of such materials in making optical fibers.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvard et al ('677) in view of the teaching of Aron nee Rosa et al (4,309,998).

Again, the Colvard et al system has been previously addressed. Colvard et al disclose many pulse parameter ranges that are within the applicant's disclosed ranges.

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However, in order to more clearly address the claimed limitations, the Aron nee Rosa et al reference is cited.

Aron nee Rosa et al disclose a device for treating ocular vascular tissue (much like Colvard et al), and more specifically disclose the use of pulses having the pulse duration, burst count and pulse separation as set forth in applicant's claims (col. 38-52).

To have provided the Colvard et al pulsed laser system with any reasonable pulse characteristics would have been an obvious consideration for one of ordinary skill in the art, particularly in view of the teaching of Aron nee Rosa et al who disclose a pulsed laser system having pulse parameters within the exact ranges set forth in applicant's claims.

Claims 48-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvard et al ('677) in view of the teaching of Adair (4,782,819).

The Colvard et al device has been addressed previously. Colvard et al fail to specifically disclose a fiber-fiber coupling at the proximal end of the probe (i.e. the use of a "trunk" fiber). Rather, Colvard et al use a lens arrangement to deliver laser pulses to the fiber optic (Figure 4).

With regard to claim 48, Colvard et al disclose the energy means (60) to generate bursts of laser light and means to focus the light into a flexible endoprobe (10). The endoprobe includes a flexible optical fiber (14) and a distal guide structure (22,24) for delivering energy to tissue. Colvard et al disclose that various probe configurations may be provided, and the probe may include a side-firing optical fiber (Figure 8). As

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addressed previously, Colvard et al disclose the various pulse characteristics and fiber diameter, as well as the distal guide structure that includes a shield member (106) extending in front of the optical fiber (Figure 5). The only feature not expressly shown by Colvard et al is the use of a trunk fiber for connecting the endoprobe to the energy source.

Adair discloses a similar device that includes a laser source connected to a flexible endoprobe. In particular, Adair teaches that the connection between the endoprobe and the laser source may be made through a "trunk" fiber (98). The examiner maintains that the use of fiber to fiber connections in lieu of lens to fiber connections is generally well known in the art and readily substitutable with each other. Further, it is noted that Adair discloses alternative probe distal ends, including various bent configurations.

To have provided the Colvard et al device with a fiber to fiber connection to the laser source, in lieu of the lens to fiber connection, would have been an obvious design consideration for one of ordinary skill in the art, particularly since Adair teaches of the use of fiber to fiber connections for the transmittance of light energy.

Claims 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvard et al ('677) and Adair ('819) in view of the teaching of Aron nee Rosa et al (4,309,998).

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As addressed previously, Colvard et al disclose various parameters for the pulse characteristics of the laser light. Aron nee Rosa et al disclose a laser system for the same procedures, and more specifically disclose the pulse count and pulse separations.

To have provided the Colvard et al pulsed laser system, as modified by the teaching of Adair, with any reasonable pulse characteristics would have been an obvious consideration for one of ordinary skill in the art, particularly in view of the teaching of Aron nee Rosa et al who disclose a pulsed laser system having pulse parameters within the exact ranges set forth in applicant's claims.

Conclusion

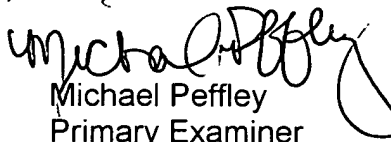
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Leckrone (4,627,436), Brinkmann et al (6,074,384) and Levine et al (6,547,779) all disclose various vascular catheters which utilize bursts of laser energy comprised of individual pulses to remove tissue. McDonald (4,601,037) discloses another laser device for treating the eye that delivers bursts of laser energy comprised of individual pulses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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May 16, 2005